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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket #97N-484S

To Whom It May Concern:

This letter is in reference to the proposal from the September 30, 1999, issue of the Federal Register where the FDA proposes to regulate allograft tissue as medical devices.

I would like to take this opportunity to voice my concern that the Food and Drug Administration is putting its energy into regulating devices where no standard may exist. As you are aware, allograft tissue has been used in orthopedic surgery for quite some time. To restrict access to allograft tissue may be a disservice to patients.

Sincerely,



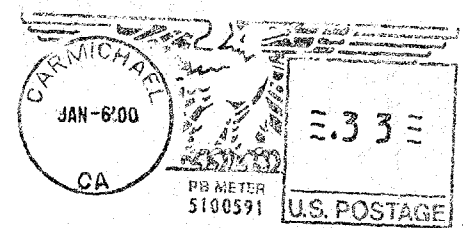
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